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09/904,186	07/12/2001	Andrew Pakula	0342/19045-US5	2874

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EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	16

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/904,186	Pakula et al
Examiner	**Art Unit**
Padmashri Ponnaluri	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 15, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *66-107* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *66-107* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1.This application is a continuation of application 08/978,381, filed on 11/25/97; which is a continuation of application 08/547,889, filed on 10/25/1995; which is a continuation-in-part of application 08/263,923, filed on 6/21/1994; which is a continuation in part of application 08/080,829, which is filed on 6/21/1993.

2.The amendment A, filed on 7/15/03 has been fully considered and entered into the application. Claims 1-65 have been canceled and new claims 66-107 have been added by the amendment A.

3.Claims 66-107 are currently pending and are being examined in this application.

4.The rejections of claims 1-37 under 35 U. S. C. . 112, second paragraph set forth in the previous office action have been withdrawn in view of cancellation of the claims.

Priority

5. Claims 66-68, and 77 may not have the benefit of the filing date of the parent application serial number 08/263,923, filed on 6/21/1994. The method for screening 'more than 1000 selected ligands per day' claimed in Claims 66-68, 77 has no clear support in parent application serial number 08/263,923.

If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

6. The instant claims 66-107 have effective filing date of parent application 08/547,889, filed on 10/25/1995.

New Rejections necessitated by the Amendment

Claim Rejections - 35 U. S. C. § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 66-68, 77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The limitation 'screening more than thousand compounds or ligands...' claimed in claims 66-68 and 77 has no clear support in the specification and the claims as originally filed. The subject matter claimed in claims 66-68, 77 broadens the scope of the invention as originally disclosed in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

9. Claims 66-107 are rejected under 35 U.S.C. 112, first paragraph, as containing

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new mater rejection.

The limitation '**selecting a plurality of ligands (or compounds) not known to bind to a target protein**' claimed in Claims 66-68, 75 and 80 has no clear support in the specification and the claims as originally filed. The subject matter claimed in claims 66-68, 75, 80 broadens the scope of the invention as originally disclosed in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

10. Claims 66-107 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims briefly recite 'a method of screening for compounds which bind to a target ligand, and the method comprises: **selecting a plurality of ligands or compounds that are not known to bind to a target protein** ; ....g) repeating steps b) to f) with more than one thousand of selected ligands until ligands that bind to target protein are identified.'

The specification description is directed to a novel method for screening chemical compounds by placing them in the presence of target proteins and determine the ability of test

ligands to increase the ration of folded target protein to the unfolded target protein. The specification no where teaches 'a method for selecting a plurality of ligands or compounds that do not bind to a target protein.' The specification does not recite how the compounds that are not known to bind to target protein are selected. The specification has not shown or described that the ligand structure or function is known such that ligands which are not known to bind to the target protein are selected. The specification does not describe that the ligands are known by the structure or function or how they are related to the target. The specification does not provide any guidance on how to select these compounds not known to bind to target, and later determine the compounds which are not known to bind to the target as compounds that bind to the target. Does applicants mean that initially the compounds structure is known such that it is determined that the compounds are not known to bind to target. The specification examples are all drawn to methods of screening of compounds that bind to a target, and none of the specification example methods are drawn to 'selecting compounds that are not known to bind to target protein.' The specification disclosure clearly does not provide an adequate representation regarding the open ended claimed method.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405

(1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to DNA compounds, this holding would be deemed to be applicable to method claims which requires a showing of sufficient identifying characteristics; to demonstrate possession of the claimed generic(s).

In the present instance, the claimed invention contains no identifying characteristics regarding the compounds not know to bind to the target protein.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 66-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are vague and indefinite by reciting in step a) selecting or providing a plurality of ligands or compounds not known to bind to a target protein; ..... g) ..... until ligands that bind to target protein are identified.' Applicants are requested to clarify if the ligands are already known as compounds that do not bind to a target protein, in step g) how is it is determined that the compounds that bind to target. It is understood that the compounds are determined as compounds that do not bind to target based on prior knowledge of the compounds

(experimental , or structural data), and further take these compounds which are already known as compounds that do not bind to target and determine the compound that bind to target. The specification does not specifically teach how the compounds are determined as compounds that do not bind to target and further use the compounds in an assay to determine the compounds which bind to target.

Claims 66-107 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 'how to select a plurality of ligands not known to bind to a target protein'. The claimed method does not recite how the ligands are selected. Were the compounds previously screened and determined as ligands not known to bind to target or the ligands are selected based on their structural or function properties, so that ligands are known as compounds that do not bind to target. Applicants are requested to include the method of selecting these ligands.

Claims 89-94 recite the limitation " said test ligand" . There is insufficient antecedent basis for this limitation in the claims or in the independent claim 80

Claims 89-94 are indefinite by reciting 'small organic molecule' in which the term 'small' is a relative term. It may be smaller compare to a bigger compound and has no metes and bounds. It is not clear what does applicant mean by small, and it is not clear relative to what the compounds are considered as small. Applicants are requested to amend the claim by reciting the size of the organic molecule.

Claim Rejections - 35 U. S. C. § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 66-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volkin et al (Harnessing Biotechnology for the 21st century, pages 298-302, August 1992) and Agrafiotis et al (US Patent 5,463,564). (NOTE that Agrafiotis et al filing date September 16, 1994 which is earlier than the effective filing date of the instant claims).

Volkin et al teach a binding assay in which a group or related and soluble, small organic compounds (relates to the plurality of test ligands of the instant claims) whose binding ability to

the target protein FGF is not known, are incubated with the target protein and the extent of the protection from thermal induced unfolding is determined by either aggregation or changes of fluorescence. Volkin et al teach that the compounds which protect FGF (target protein) from unfolding have potential development as pharmaceuticals to stabilize FGF compositions. Volkin et al teach that the binding assay method is convenient technique to examine ligand interactions. Volkin et al teach fluorescence spectroscopy is a convenient method to monitor structural integrity of FGF.

The claimed invention differs from the prior art teachings by reciting 'selecting plurality of ligands not known to bind to target protein; ...screening more than 1000 compounds'. NOTE that in absence of teaching the support for 'selecting a plurality of compounds not known to bind to target protein' is considered as new matter. Even if applicants prove the support for the limitation, it would have been obvious to one skilled in the art at the time the invention was made to use the assay method taught by Volkin et al to identify a ligand that bind to a target protein, without prior information or knowledge of the ligand. Agrafiotis et al teach methods for screening a chemical library (or compounds) that bind to a target protein. Agrafiotis does not recite that the chemical library compounds are known or already known compounds are used (prior knowledge of the compounds) in the method. Thus, the reference compounds are not known to bind to target protein are used in the screening assay method. Thus, it would have been obvious to one skilled in the art to use compounds without prior knowledge of their binding to target can be used in the method for screening for compounds that bind to target.

Further the recitation 'more than 1000 compounds per day' or rapid screening is not considered as patentably distinct from screening one compound. The limitation 'more than 1000 compounds per day' is dependent on the equipment and the automation methods used in the laboratory and is not patentably distinct from screening a single compound. However, Agrafiotis et al teach a system and method of automatically generating chemical compounds with desired properties. The reference teaches a diverse chemical library is robotically generated and analyzed. The reference teaches a computer based system and method for automatically generating chemical library and analyzing the chemical library robotically. The reference teaches that the chemical library is analyzed for fluorescence properties. The reference teaches that the library may contain 1000 to 5000 members and are screened or analyzed in a competitive binding assay. The reference teaches that using the system a plurality of structure activity models may be tested and evaluated in parallel. The reference teaches that the system can be adapted to generate chemical compounds having any useful properties that depend upon structure, composition or state. Th reference teaches that the present invention enables the automatic and intelligent synthesis and screening of very large numbers of chemical compounds which would refer to high throughput screening or more than thousands compounds per day of the instant claims.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to screen more than one thousand compounds which would effect the folding and unfolding of the target compounds since Agrafiotis et al teach the use of the robotic methods in screening large number of compounds and Volkin et al teach the method of screening for compounds which

would effect the folding and unfolding of the target compounds. A person skilled in the art would have been motivated to use the robotic methods taught by Agrafiotis et al with the methods taught by Volkin et al such that a large number of compounds are screened.

15. Claims 66-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsai et al (Pharmaceutical Research, vol. 10, May 1993, pages 649-659) and Agrafiotis et al (US Patent 5,463,564). (NOTE that Agrafiotis et al filing date September 16, 1994 which is earlier than the effective filing date of the instant claims).

Tsai et al teach a rapid screening procedure to identify compounds, including small organic compounds, which stabilize heat induced unfolding of a target protein. A plurality of compounds whose binding ability to the target protein FGF is not known, are incubated with the target protein and the amount or rate of thermal induced unfolding is determined by either aggregation or changes in fluorescence. Compounds that are promising, at least one, are than assayed for their effect on a bioactivity of the target protein. Tsai et al teach that the compounds are to be developed as part of pharmaceutical compositions for wound healing.

The claimed invention differs from the prior art teachings by reciting 'screening more than 1000 compounds per day'. Note that the recitation 'more than 1000 compounds per day' or rapid screening is not considered as patentably distinct from screening one compound. The limitation 'more than 1000 compounds per day' is dependent on the equipment and the automation methods used in the laboratory and is not patentably distinct from screening a single compound. However, Agrafiotis et al teach a system and method of automatically generating chemical compounds with

desired properties. The reference teaches a diverse chemical library is robotically generated and analyzed. The reference teaches a computer based system and method for automatically generating chemical library and analyzing the chemical library robotically. The reference teaches that the chemical library is analyzed for fluorescence properties. The reference teaches that the library may contain 1000 to 5000 members and are screened or analyzed in a competitive binding assay. The reference teaches that using the system a plurality of structure activity models may be tested and evaluated in parallel. The reference teaches that the system can be adapted to generate chemical compounds having any useful properties that depend upon structure, composition or state. Th reference teaches that the present invention enables the automatic and intelligent synthesis and screening of very large numbers of chemical compounds which would refer to high throughput screening or more than thousands compounds per day of the instant claims.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to screen more than one thousand compounds which would effect the folding and unfolding of the target compounds since Agrafiotis et al teach the use of the robotic methods in screening large number of compounds and Tsai et al teach the method of screening for compounds which would effect the folding and unfolding of the target compounds. A person skilled in the art would have been motivated to use the robotic methods taught by Agrafiotis et al with the methods taught by Tsai et al such that a large number of compounds are screened in a single day.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U. S. P. Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U. S. P. Q. 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 U. S. P. Q. 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 U. S. P. Q. 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

17.Claims 66-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 5,679,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite exactly same method as the reference and only differ by reciting '...more than 1000 compounds or test ligands are screened ,' which is not patentably

distinct compare to the reference claimed method, since the reference teaches all the method steps.

18. Claims 66-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,585,277. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims differ by reciting that more than 1000 compounds or test ligands are screened in a single day, which is not patentably distinct compare to the reference claimed method, since the reference teaches a rapid and large scale screening method.

Response to Arguments

19. Applicant's arguments filed on 7/15/03 regarding the support and priority of the instant claim limitations have been fully considered but they are not persuasive.

Applicants in the response filed on 7/15/03 state that the newly submitted claims are directed to "rapid, high throughput methods," have the benefits of 06/21/94 filing date of the '582 patent and as well as in the Judge's opinion on allegations of infringement of two US Patents 5,585,277 and '582 patent.

Applicants arguments have been considered and are not persuasive, since the instant application does not have support for the recitation of 'screening 1000 or more than 1000 ligands per day.'.

Applicants argue that the specification of the '582 patent clearly states, particularly on page 2, lines 17-19: " there is need in the art for rapid, cost effective, high-throughput assay that enables the screening of large numbers of compounds ....."

The recitation of **'rapid, cost effective, high throughput assays does not specifically relate to the instant claim recitation of 'screening 1000 or more compounds per day'.** Further the recitation applicants relying in the specification is in the background section, which is reciting the state of the prior art, and what is required to be done in the field, it does not support the written description of the instant claim limitation.

Applicants further point out that the specification page 10, line 17 to page 11, line 2 of the '582 patent: ' for the purpose of high-throughput screening....' which does not have support for the instant claimed limitations.

Applicants state that the Examples 9 (specification page 36, lines 6-9) and 10 (specification page 39, lines 9-11) are drawn to high-throughput screening of 3,600 compounds and 4000 compounds respectively.

Applicants arguments have been considered and are not persuasive. The instant specification Examples 9 and 10 are drawn to screening high-throughput screening of ligands for specific receptors (target). Example 9 recites the screening assay for ligands for Human Carbonic

Anhydrase. Example 9 or page 36, lines 6-9 of the instant specification does not recite screening 3,600 compounds. Thus, example 9 does not support the instant claim limitation. And even if the example recites screening 3, 600 compounds, does not support the instant claim limitation, since the instant claim is not drawn to screening for ligands of a specific target as in Example 9.

Example 10 and page 39, 9-11 of the instant specification does not support the instant claim limitation. In page 39, the specification in Section C) recites, "3,600 compounds have been screened for interaction with HNE." This limitation would not support the instant claim limitation "screening several thousand ligands per day" (claim 77), or "excess of one thousand selected compounds per day" (claim 67), since the specification does not recite the assay or screening of 3,600 compounds was done in a single day. And further this limitation would not support the instant claims 66, 68 limitation "more than 1,000 of said selected ligands or compounds", because example 10, section C) is drawn to screening of selected 3,600 compounds for interaction with HNE, which is different from the instant claim method of screening for compounds that bind to a target.

Applicants further argue that these limitations have support in the specification based on Judge Slate's statement regarding the term "rapid, large scale screening .... means that several thousand test ligands are to be screened through a process which can be completed within number of hours...." NOTE that applicants have not made of record of the Judge's opinions filed in the Scriptgen Pharmaceuticals, Inc. V. 3-Dimensional Pharmaceuticals, Inc., Civil Action No. 98-583-GMS in the instant application. Applicants arguments have been considered and are not

persuasive, since Judge Slate's statement was not relevant to the instant application new matter rejections or priority date, and further the statement was made after the filing date of the instant application, not at the time of the invention was made. At the time of filing date of the instant application applicants have not shown that more than thousand compounds were screened in the claimed method.

20. Applicant's arguments with respect to art rejections of claims 1-37, filed on 7/15/03 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. No claims are allowed.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Examiner
Technology Center 1600
Art Unit 1639
19 February 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER

John J. Doll, Director
Technology Center 1600